

## LCD L27477 - Cancer Chemotherapeutic Agents



### Contractor Information

**Contractor Name:**

Highmark Medicare Services, Inc.

**Contractor Number:**

12102, 12202, 12302, 12501, 12301, 12201, 12401, 12402, 12101, 12502

**Contractor Type:**

MAC Part A & B

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### LCD Information

**LCD Database ID Number**

L27477

**LCD Title**

Cancer Chemotherapeutic Agents

**Contractor's Determination Number**

L27477

**AMA CPT/ADA CDT Copyright Statement**

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**CMS National Coverage Policy**

Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.

CMS On-line Manual Pub. 100-4, Chapter 12, Section 30.5F

CMS Publication, IOM 100-02, Medicare Benefit Policy Manual, Transmittal No. 96, Change Request #6191, October 24, 2008, updates the authoritative compendia and related instructions used in determining medically accepted indications of drugs and biologicals used off-label in anti-cancer chemotherapeutic regimens.

**Primary Geographic Jurisdiction**

Pennsylvania, Maryland, District of Columbia, New Jersey, Delaware

**Oversight Region**

Central Office

**Original Determination Effective Date**

For services performed on or after 07/11/2008

**Original Determination Ending Date**

N/A

**Revision Effective Date**

For services performed on or after 01/14/2010

**Revision Ending Date**

N/A

**Indications and Limitations of Coverage and/or Medical Necessity**

*Compliance with the provisions in this policy may be monitored and addressed through post payment data analysis and subsequent medical review audits.*

Several cancer chemotherapeutic agents and regimes have been developed and approved by the Food and Drug Administration (FDA) to treat various types of cancer. The intended mechanism of action is to interfere with or prevent the growth of malignant (cancerous) cells.

**FDA-approved Use for Chemotherapeutic Agents**

Generally, cancer chemotherapeutic agents are covered only if all of the following requirements are met:

- Documentation is present to support that the drug is safe and effective and is being administered for an approved indication.
- Documentation in the patient's medical record supports the medical necessity of administering the chemotherapy drug to that individual patient.
- Documentation in the patient's medical record supports that the chemotherapy drug was administered as billed.

Therefore, payment may be made for an FDA-approved chemotherapeutic drug or biological, if:

- It was injected on or after the date of the FDA's approval;
- It is reasonable and necessary for the individual patient; and
- All other applicable coverage requirements are met.

**FDA Unlabeled Use for Chemotherapeutic Agents**

There are many reasons to consider an unlabeled use for a cancer chemotherapy agent. Some of these are:

- Drugs may be effective for many other cancers in addition to the ones that were considered in the primary labeling of the drug.
- Many chemotherapeutic agents are given in combinations. Any one of the drugs in the combination may not have been approved in the initial labeling of the products. In addition the combination of effective chemotherapeutic agents changes over time.
- Cancer chemotherapeutic agents are always changing and improving over time
- Oncologists are often left with few approved treatment options if initial treatment regimens have failed.

If a physician is contemplating the use of an FDA-unlabeled anti-cancer drug or biological the following steps should be followed.

1. Initially, one of the following drug compendia should be consulted to find a list approved chemotherapeutic agents and their list of indications.
  - American Hospital Formulary Service Drug Information (AHFS-DI)
  - National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (effective 06/05/2008)
  - Thomson Micromedex DrugDex (effective 06/10/2008)
  - Clinical Pharmacology (effective 07/02/2008)

In review of these compendia if the use of the chemotherapeutic agent is supported by any one of these four compendia AND the use is NOT listed as "not indicated, unsupported, not recommended" or equivalent terms in any of the other three compendia, the agent may be approved.

2. In those circumstances when the unlabeled use of the chemotherapeutic agent is not listed in any of the compendia or is listed as insufficient data or investigational its use, the use of the drug may be supported by clinical research that appears in peer reviewed medical literature. Peer reviewed medical literature includes scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts. This does not include in-house publications of pharmaceutical manufacturing companies or abstracts (including meeting abstracts).

Coverage will be determined based on the results of peer reviewed medical literature published in the regular editions of the following publications, not to include supplement editions privately funded by parties with a vested interest in the recommendations of the authors:

- American Journal of Medicine

- o Annals of Internal Medicine;
- o Annals of Oncology
- o Annals of Surgical Oncology
- o Biology of Blood and Marrow Transplantation
- o Blood
- o Bone Marrow Transplantation
- o British Journal of Cancer
- o British Journal of Hematology
- o British Medical Journal
- o Cancer
- o Clinical Cancer Research
- o Drugs
- o European Journal of Cancer (formerly The European Journal of Cancer and Clinical Oncology)
- o Gynecologic Oncology
- o International Journal of Radiation, Oncology Biology, and Physics
- o The Journal of the American Medical Association
- o Journal of Clinical Oncology
- o Journal of the National Cancer Institute
- o Journal of the National Comprehensive Cancer Network (NCCN)
- o Journal of Urology
- o Lancet
- o Lancet Oncology
- o Leukemia
- o The New England Journal of Medicine
- o Radiation Oncology

3. Unlabeled uses of cancer chemotherapeutic agents may also be considered medically accepted if determined to be the community standard of care and to be medically accepted as safe and effective for the particular use. In order to determine if a chemotherapeutic agent meets the level of community standard of care, the following may be used:

Peer reviewed medical literature in journals other than those journals cited above also can be used to establish a community level standard of care. Again this literature includes scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts. This does not include in-house publications of pharmaceutical manufacturing companies or abstracts (including meeting abstracts). Furthermore, the level of evidence in each article must be determined.

Levels of evidence as defined below will be used to assess research and to determine a grade of recommendation for a particular medical treatment. These levels are described below:

Level 1: Randomized controlled trials/meta analyses

Level 2: Cohort studies

Level 3: Case controlled studies

Level 4: Cross sectional surveys, case reports, or case series

Level 5: Expert opinion

If the peer-reviewed literature is a Level 1 study, the use of that specific chemotherapeutic agent is considered to be the community standard and the agent is covered. However, if the peer-reviewed literature is a Level 2, 3, or 4 study two or more articles by different authoring groups are required to establish the use of the chemotherapeutic agent as the community standard before the agent will be covered. If the literature is only Level 5 then the chemotherapeutic agent has not been established as a community standard and will not be covered.

4. If the provider decides to use a chemotherapeutic agent that does not have FDA-approved labeling, the evidence used to make that decision (information in the compendia, established guidelines [for example guidelines developed by the National Comprehensive Cancer Network, Association of Community Cancer Center Compendia, American Society of Clinical Oncology], research studies in approved peer-reviewed medical journals, etc.) must be retained. This information must be retained in the patient's record either as a hard copy of the reference material itself or citations of the reference material. This information must be submitted whenever requested.
5. If, however, a use is identified as not indicated by CMS or the FDA, or if a use is specifically identified as not indicated in one or more compendia listed or the contractor determines, based on peer reviewed medical literature that a particular use of a drug is not safe and effective, the off labeled usage is not supported and, therefore, the drug is not covered.

Note: Payment for the administration of a chemotherapy injection or infusion may be paid when provided on the same day as an E and M service, other than 99211, if the E and M service represents a separate and significantly identifiable service. Modifier 25 must be used. A different diagnosis code is not required.

For Additional Drug and Biological Coverage, see L27473.

See Billing and Coding Article A47797.

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## Coding Information

### Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

11x	Hospital-inpatient (including Part A)
12x	Hospital-inpatient or home health visits (Part B only)
13x	Hospital-outpatient (HHA-A also) (under OPSS 13X must be used for ASC claims submitted for OPSS payment -- eff. 7/00)
83x	Special facility or ASC surgery-ambulatory surgical center (Discontinued for Hospitals Subject to Outpatient PPS; hospitals must use 13X for ASC claims submitted for OPSS payment -- eff. 7/00)
85x	Special facility or ASC surgery-rural primary care hospital (eff 10/94)

### Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

0636	Drugs requiring specific identification-detailed coding (eff 3/92)
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### CPT/HCPCS Codes

Italicized and/or quoted material is excerpted from the American Medical Association, *Current Procedural Terminology (CPT)* codes.

**See revision history for code updates effective retroactive to 01/01/2010.**

J9000 - J9999	INJECTION, DOXORUBICIN HYDROCHLORIDE, 10 MG - NOT OTHERWISE CLASSIFIED, ANTINEOPLASTIC DRUGS
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### ICD-9 Codes that Support Medical Necessity

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

XX000	Not Applicable
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### Diagnoses that Support Medical Necessity

Not Applicable

### ICD-9 Codes that DO NOT Support Medical Necessity

Not Applicable

### ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

## Diagnoses that DO NOT Support Medical Necessity

Not Applicable

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## Other Information

### Documentation Requirements

1. All documentation must be maintained in the patient's medical record and available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service(s)). The record must include the physician or non-physician practitioner responsible for and providing the care of the patient.
3. The submitted medical record should support the use of the selected ICD-9-CM code(s). The submitted CPT/HCPCS code should describe the service performed.
4. Physicians or suppliers must be able to produce copies of relevant supporting full-text articles, guidelines, and/or supporting literature when an unlabeled use does not appear in at least one of the major compendia mentioned or is listed as insufficient data or investigational. Abstracts, opinions, or book chapters are not acceptable. Availability of this specifically required documentation is indicated by use of the KX modifier on the submitted claim. This material must be submitted whenever requested.

### Appendices

N/A

### Utilization Guidelines

In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

### Sources of Information and Basis for Decision

*Highmark Medicare Services is not responsible for the continued viability of websites listed.*

American Society of Clinical Oncology Web Site. Available at <http://www.asco.org/portal/site/ASCO>. Accessed May 15, 2007.

Centre for Evidence Based Medicine Web Site. Available at <http://www.cebm.net>. Accessed May 15, 2007

Levels of Evidence in AFP. American Family Physician. 2007. Available at <http://www.aafp.org/online/en/home/publications/journals/afp/afplevels.html>. Accessed May 15, 2007.

National Comprehensive Cancer Network Web Site. 2007. Available at <http://www.nccn.org>. Accessed on May 15, 2007.

National Guideline Clearinghouse Web Site. 2007. Available at <http://www.guideline.gov>. Accessed May 15, 2007.

U.S. Food and Drug Administration. "Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices. Available at <http://www.fda.gov/oc/ohrt/irbs/offlabel.html>. Accessed May 9 2007.

Other Contractors' Policies

Highmark Medicare Services Contractor Medical Directors

### Advisory Committee Meeting Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Directors. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the appropriate specialty (ies).

CAC/IAC Distribution: 04/01/2008

### Start Date of Comment Period

04/01/2008

### End Date of Comment Period:

05/15/2008

**Start Date of Notice Period**

05/23/2008

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L27477

**Revision History Explanation**

Date	Policy #	Description
01/13/2010	L27477	LCD effective 01/14/2010. The following CPT/HCPCS code changes are effective retroactive to 01/01/2010. New codes added: J9155, J9171, and J9328. Code deleted: J9170. These codes are in a range.
10/27/2009	L27477	LCD effective 10/28/2009. Updated to include reference to Billing and Coding article A47797, Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents.
12/12/2008	L27477	LCD effective 12/12/2008 for Pennsylvania Part B. LCD is now effective for DC Part A and DCMA Part B; Delaware Part A and Part B; Maryland Part A and Part B; New Jersey Part A and Part B; Pennsylvania Part A and Part B. The following CPT/HCPCS code changes will be effective 01/01/2009: Code J9182 deleted. Code description changes: J9000, J9001, J9010, J9015, J9017, J9020, J9040, J9045, J9050, J9098, J9100, J9110, J9120, J9150, J9151, J9160, J9165, J9170, J9181, J9185, J9190, J9200, J9201, J9206, J9208, J9209, J9211, J9212, J9213, J9214, J9215, J9216, J9230, J9265, J9266, J9268, J9270, J9300, J9310, J9320, J9340, J9350, J9355, J9357, J9360, J9390, J9600. Codes inserted: J9033, J9207.
11/19/2008	L27477	LCD revision effective 11/20/2008. Compendia and related instructions updated in the Indications and Limitations of Coverage and/or Medical Necessity section, per CR 6191 (non-discretionary update). Please see that section for effective dates for each compendium.
11/14/2008	L27477	LCD effective 11/14/2008 for New Jersey Part B and Delaware Part A. LCD is now effective for DC Part A and DCMA Part B; Delaware Part A and Delaware Part B; Maryland Part A and Maryland Part B; New Jersey Part A and New Jersey Part B; Pennsylvania Part A.
08/29/2008	L27477	LCD effective 09/01/2008 for New Jersey Part A. Effective 09/01/2008, New Jersey Part A will be added to the other jurisdictions already effective: DC Part A and DCMA Part B; Maryland Part A and Maryland Part B; Pennsylvania Part A; and Delaware Part B.
08/01/2008	L27477	LCD effective 08/01/2008 for DC Part A, Maryland Part A, and Pennsylvania Part A. LCD is now effective for DC Part A and DCMA Part B; Maryland Part A and Maryland Part B; Pennsylvania Part A; and Delaware Part B.
05/23/2008	L27477	Original LCD posted for notice. LCD to become effective 07/11/2008 for Maryland Part B, DCMA Part B and Delaware Part B.
04/01/2008	Draft J12-D5	Original LCD posted for comment.

**Last Reviewed On**

01/12/2010

**Related Documents**

This LCD has no Related Documents.

**LCD Attachments**

There are no attachments for this LCD.

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or use the [Medical Policy Search](#) or the [Advanced Search](#).

## Billing & Coding Article: Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents



### Contractor Information

**Contractor Name:**

Highmark Medicare Services, Inc.

**Contractor Number:**

12102, 12202, 12302, 12501, 12301, 12201, 12401, 12402, 12101, 12502

**Contractor Type:**

MAC Part A & B

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### Article Information

**Article ID Number**

A47797

**Article Type**

Article

**Key Article**

No

**Article Title**

Approved Drugs and Biologicals; Includes Cancer Chemotherapeutic Agents

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**Primary Geographic Jurisdiction**

Pennsylvania, Maryland, District of Columbia, NEW JERSEY, DELAWARE

**Original Article Effective Date**

07/11/2008

**Article Revision Effective Date**

01/14/2010

**Article Ending Effective Date**

N/A

**Article Text**

Coding Guidelines

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This information does not take precedence over CCI edits. Please refer to CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

If the "J" code descriptor can be multiplied to reflect the dosage being administered, use the J-code, with the appropriate number of units which reflect the dosage given.

It is not appropriate to use the "J" code with a multiplier in the units' field, when there is another "J" code, which more closely describes the amount given.

It is not appropriate to bill for the full amount of a drug when it has been split between two or more patients. Bill only for the amount given to each beneficiary.

NOC codes should only be reported for those drugs that do not have a valid HCPCS code which describes the drug being administered.

When appropriate, the NOC code is selected based upon the therapeutic value of the drug (e.g., J8999 Prescription drug, oral, chemotherapeutic, NOS; J3490 Unclassified drugs, etc.)

When billing with an NOC code, include on the claim, the narrative description reflective of the agent and the dose administered.

Where the sole purpose of an office visit was for the patient to receive an injection, (96372, 96373, 96374, and 96379) payment may be made only for the injection service (if it is covered).

Conversely, injection services (codes 96372, 96373, 96374, and 96379) included in the Medicare Physician Fee Schedule (MPFS) are not paid for separately, if the physician is paid for any other physician fee schedule service furnished at the same time.

The injection or infusion of certain cancer drugs not used to treat cancer, monoclonal antibodies and cancer chemotherapy injections (CPT codes 96401-96549) will be paid in addition to a significant separately identifiable Evaluation and Management service performed on the same day, when billed.

The drug is separately payable. All injection claims must include the specific name of the drug and dosage. Identification of the drug enables proper payment for the services.

#### Off-label Usage of an FDA-Approved Drug

An unlabeled use of a drug is a use that is not included as an indication on the drug's label as approved by the FDA. FDA-approved drugs used for indications other than what is indicated on the official label may be covered under Medicare if the criteria below are met.

An off-label usage of an FDA-approved drug will be considered for coverage when there are no specific contraindications and one of the following criteria is met.

1. Its usage is supported by one or more citations in at least one of the drug compendia listed below, and the usage is not listed as "not indicated, unsupported, not recommended" or equivalent terms in any of the compendia listed below:
  - o American Hospital Formulary Service Drug Information (AHFS-DI)
  - o National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (effective 06/05/08)
  - o Thomson Micromedex DrugDex (effective 06/10/2008)
  - o Clinical Pharmacology (effective 07/02/2008)
2. The use is supported by clinical research that appears in peer-reviewed medical literature. This applies only when an unlabeled use does not appear in any of the compendia or is listed as insufficient data or investigational. Peer-reviewed medical literature includes scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts. This does not include in-house publications of pharmaceutical manufacturing companies or abstracts (including meeting abstracts). Furthermore, the level of evidence in each article must be determined.

Levels of evidence, as defined below, will be used to assess research and to determine a grade of recommendation for a particular medical treatment.

Level 1: Randomized controlled trials/meta analyses

Level 2: Cohort studies

Level 3: Case controlled studies

Level 4: Cross sectional surveys, case reports, or case series

Level 5: Expert opinion

If the peer-reviewed literature is a Level 1 study, the use of that specific therapeutic agent is considered to be the community standard and the agent is covered. However, if the peer-reviewed literature is a Level 2, 3, or 4 study two or more articles by different authoring groups are required to establish the use of the therapeutic agent as the community standard before the agent will be covered. If the literature is only Level 5 then the agent has not been established as a community standard and will not be covered. The design, conduct and analysis of trials are important factors as well. For example, a well designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size.

In determining whether there is supportive clinical evidence for a particular use of a drug, the quality of the published evidence must be considered. Such consideration involves the assessment of the following study characteristics:

- The adequacy of the number of subjects;
- The response rate;
- The effect on key status and survival indications. That is, the effect on the patient's well-being and other responses to therapy that indicate effectiveness (e.g., reduction in mortality, morbidity, signs and symptoms);
- The appropriateness of the study design, that is, whether the experimental design in light of the drugs and conditions under investigation is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.); and
- The prevalence and life history of the disease when evaluating the adequacy of the number of subjects and the response rate.

Regardless of the evidence supporting coverage for a particular off-label use, payment may only be made if the use is reasonable and necessary for the treatment of illness or injury of the specific patient receiving the drug.

Services related to non-covered services or drugs are also not covered (e.g., administration services).

When the drug is purchased by the beneficiary, or when the drug was supplied without charge by the manufacturer, it should NOT be billed to Medicare by the provider, even with a submitted charge of \$0.00.

If the provider decides to use a therapeutic agent that does not have FDA-approved labeling, the evidence used to make that decision (information in the compendia, established guidelines, research studies in approved peer-reviewed medical journals, etc.) must be retained. This information must be retained in the patient's record either as a hard copy of the reference material itself or citations of the reference material. Retention of this specifically required documentation on file is indicated by use of the KX modifier on the submitted claim. This material must be submitted whenever requested.

If a use is identified as not indicated by CMS or the FDA, or if a use is specifically identified as not indicated in one or more compendia listed or the contractor determines, based on peer reviewed medical literature, that a particular use of a drug is not safe and effective, the off labeled usage is not supported and, therefore, the drug is not covered.

#### Specific Coding Guidelines

Administration of Drugs (96365-96379) and Administration of Certain Monoclonal Antibody Agents, Anti-Neoplastic Agents for Treatment of Noncancer Diagnoses and Chemotherapy Administration (96401, 96402, 96409, 96411, 96413, 96415-96417)

The chemotherapy administration codes apply to parenteral administration of non-radionuclide antineoplastic drugs and antineoplastic agents provided for the treatment of noncancer diagnoses (e.g. cyclophosphamide for autoimmune conditions), or to substances such as monoclonal antibody agents and other biologic response modifiers. Administration of anti-anemia drugs and anti-emetic drugs by injection or infusion for cancer patients is not considered chemotherapy administration. Such services are reported using the following codes as appropriate: 96365-96368 and 96372, 96374-96376.

The chemotherapy administration codes may be reported when the clinical indication for the drug being administered satisfies the definition above.

Chemotherapy administration codes include confirmation or recalculation of doses based upon the condition of the patient on the day of chemotherapy administration.

When administering multiple infusions, injections, or combinations, only one "initial" drug administration service code should be reported per patient per day, unless protocol requires that two separate IV sites must be used. The initial code is the code that best describes the key or the primary reason for the encounter, and is reported irrespective of the order in which the infusions or injections occur.

If an injection or infusion is of a subsequent or concurrent nature, even if it is the first such service within that group of services, the subsequent or concurrent code from the appropriate section should be reported (e.g., the first IV push given subsequent to an initial one-hour infusion is reported using a subsequent IV push code).

There is no code for concurrent administration of chemotherapeutic drugs. Multiple drugs given at the same session are considered to be sequential, rather than concurrent. The services are reported with 96411 for IV push administration of additional drugs/substances at the same session and 96417 for IV infusion administration of additional drugs/substances at the same session.

When reporting codes for which infusion time is a factor, use the actual time over which the infusion is administered. Services leading up to the infusion and to conclude the infusion are included in the infusion service and not separately reported. The services include starting the IV and monitoring the patient post-infusion. Standard clinical practice is to document the actual start and stop times in the patient's medical records. This would ensure that the times are accurate in the event there are interruptions or delays during the infusion process. Flow sheets kept by personnel during infusion services help to identify proper infusion times.

The first hour initial codes are defined as "up to one hour". This eliminates the need to report the 52 modifier to inform Medicare of durations of less than 1 hour.

Report 96415 for infusion intervals of greater than 30 minutes beyond 1 hour increments. Report 96415 in conjunction with 96413.

Do not report 96360 if performed as a concurrent infusion service. Report 96361 to identify hydration furnished as a secondary or subsequent service after a different initial service is administered through the same IV access. Report 96366, 96367, 96375 or 96376, to identify therapeutic, prophylactic or diagnostic drug infusion or injection when provided as a secondary or subsequent service in association with 96413.

Report 96417 in conjunction with 96413. Report 96417 only once per sequential infusion.

The appropriate E&M CPT code (other than 99211) should be reported utilizing modifier 25 in addition to chemotherapy administration if a significant separately identifiable E & M service is performed. For an E&M service provided on the same day, a different diagnosis is not required.

Report 96523 if it is the only service provided that day. If there is a visit or other drug administration service provided on the same day, payment for 96523 is included in the payment for the other service.

If performed to facilitate an infusion or injection, the following are included and are not reported separately:

- Use of local anesthesia
- IV start
- Access to indwelling IV, subcutaneous catheter or port
- Flush at conclusion of infusion
- Standard tubing, syringes and supplies
- Preparation of chemotherapy agent(s)
- Report CPT code 36593 for declotting a catheter or port.

Report separate codes for each parenteral method of administration employed when therapy is administered by different techniques. Medications (e.g., antibiotics, steroidal agents, antiemetics, narcotics analgesics) administered independently or sequentially as supportive management of chemotherapy or certain monoclonal antibody administration should be separately reported using 96360, 96361, 96365 or 96379 as appropriate. Report the specific service as well as code(s) for the specific substance or drug(s) provided.

The fluid used to administer the drug(s) is considered hydration and is not separately reportable. An infusion consisting of three substances in a single bag is not intended to be reported as three separate infusion services.

#### Hydration Administration (96360, 96361)

Medicare currently permits separate payment of hydration therapy provided sequentially (but not concurrently) to chemotherapy infusion.

Codes 96360 and 96361 are intended to report a hydration IV infusion consisting of a prepackaged fluid and/or electrolyte solutions (e.g., normal saline, D5-1/2 normal saline +30mEq KC1/liter), but are not used to report infusion of drugs or other substances. Hydration IV infusion typically requires direct physician supervision for purposes of consent, safety oversight or intra-service supervision of staff. Typically such infusions require little special handling to prepare or dispose of, and staff which administer these do not typically require advanced training. After initial set up, infusion typically entails little patient risk and thus little monitoring. Further instructions regarding hydration and its use may be found in the CPT Manual, particularly with regard to

facilities. In addition, certain coding combinations are not permissible by the CCI edits.

### Discarded Drugs and Biologicals

The CMS encourages physicians, hospitals and other providers to schedule patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner. However, if a physician, hospital or other provider must discard the remainder of **a single use vial or other single use package** after administering a dose/quantity of the drug or biological to a Medicare patient, the program provides payment for the amount of drug or biological discarded along with the amount administered, up to the amount of the drug or biological as indicated on the vial or package label. When billing drugs, units of service must be billed in multiples of the dosage specified in the full HCPCS descriptor. This descriptor does not always match the dose given. The units billed must correspond with the smallest dose (vial) available for purchase from the manufacturer(s) that could provide the appropriate dose for the patient. The following examples will help illustrate some of these points:

#### Example of choice of vial size

HCPCS for drug A indicates 1 unit = 30 mg

Drug A doses available from the manufacturer: 60 mg vial and 90 mg vial

The amount prescribed for the patient is 48 mg. If the provider uses a 90 mg vial to administer the dose, the provider may only bill only 2 units (rather than 3 units) as the doses available from the manufacturer allow the prescribed amount to be administered with a 60 mg vial.

Additionally, if after administering the prescribed dosage of any given drug, the provider must discard the remainder of a single-use vial or other package, Medicare may cover the amount of the drug discarded along with the amount administered. HCPCS modifier JW is defined as "drug or biological amount discarded/not administered to any patient" and is used on claims to indicate drug wastage when the above measures have been taken.

The amount administered and the amount wasted must be billed on the same claim. The amount administered is on a separate detail line from the amount wasted, which is indicated with the modifier JW (when applicable). The modifier JW would not be used, however, for claim billings when the long code description already includes the total of the amount administered plus any amount wasted. The medical record must also additionally record the amount of the drug given and the amount wasted (for single use vials) or the amount wasted will not be reimbursed.

#### Examples of wastage of single use vials when JW is applicable:

Currently, onabotulinumtoxinA (Botox) is available only in a 100-unit size and has a short shelf life. Often, a patient receives less than a 100-unit dose. Because this is a very expensive drug, physicians are encouraged to schedule patients in such a way that they can use Botox most efficiently.

Code J0585 is defined as onabotulinumtoxinA, per unit. The physician schedules three Medicare patients to receive Botox on the same day and administers thirty (30) units to each patient. The remaining ten (10) units are billed to Medicare on the account of the last patient. Therefore, thirty (30) units are billed on behalf of the first two patients. Forty (40) units are billed on behalf of the last patient seen because the physician had to discard ten (10) units at that point due to the limited shelf life of the drug. The documentation for the last patient should indicate thirty (30) units administered to the patient and ten (10) units wasted. If the ten (10) units wasted is not indicated in the medical record, the physician will only be reimbursed for the thirty (30) units administered to the patient.

The first two patients are billed with J0585, thirty (30) units each. The third patient is billed as J0585, thirty (30) units on one line and J0585 JW, ten (10) units on the second line. In the record, the documentation for the last patient should indicate thirty (30) units administered to the patient and ten (10) units wasted. If the ten (10) units wasted are not indicated in the medical record, the physician will only be reimbursed for the thirty (30) units administered to the patient.

If a physician must discard the remainder of a vial after administering it to a Medicare patient, the program covers the amount of drug discarded along with the amount administered. The example below from another Contractor would be illustrative of this situation:

#### Per Unit Example, Single Patient:

A physician must administer 15 units of onabotulinumtoxinA to a Medicare patient, and it is not practical to schedule another patient who requires this botulinum toxin, as the physician has only one patient who requires botulinum toxin, or the physician sees the patient for the first time and does not know the patient will be

receiving the drug upon scheduling. Code J0585, onabotulinumtoxinA, per unit, is billed for fifteen (15) units on the first line and J0585, eighty-five (85) units, JW, are billed on the second line. Again, the record must reflect the wastage.

Example illustrating the billing of wastage where JW is not applicable:

"If 2.5 milligrams of Zoledronic Acid is administered, it is appropriate to bill for 3 units, as the HCPCS defines the unit for Zoledronic Acid as 1 milligram." The example would be billed without a JW modifier, as the wastage is already considered reimbursed in the billing of the 3 units. (2.5 mg given and 0.5mg wasted). The entire 3mg expense to the provider is covered with one detail line by billing the J code multiplied by three without an additional modifier. The medical record will document the 2.5 mg injected and the 0.5mg of wastage. If an additional detail line were billed with the JW modifier, it would imply that wastage had been billed twice. This would not be supported in the medical record, resulting in an overpayment.

As a reminder, drug wastage cannot be billed if none of the drug was administered (such as a missed appointment by the patient).

When processing all drugs except those provided under the Competitive Acquisition Program for Part B drugs and biologicals (CAP), local contractors may require the use of the modifier JW to identify unused drug or biologicals from single use vials or single use packages that are appropriately discarded. This modifier will provide payment for the discarded drug or biological.

The JW modifier must not be used on Medicare Part B Drug CAP claims; providers shall not code for wastage for drugs furnished under the CAP. Claims for drugs provided under CAP submitted with the JW modifier will be treated as unprocessable.

**NOTE: Multi-use vials are not subject to payment for discarded amounts of drug or biological.**

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## Coding Information

### Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

11x	Hospital-inpatient (including Part A)
12x	Hospital-inpatient or home health visits (Part B only)
13x	Hospital-outpatient (HHA-A also) (under OPSS 13X must be used for ASC claims submitted for OPSS payment -- eff. 7/00)
18x	Hospital-swing beds
21x	SNF-inpatient, Part A
22x	SNF-inpatient or home health visits (Part B only)
23x	SNF-outpatient (HHA-A also)
83x	Special facility or ASC surgery-ambulatory surgical center (Discontinued for Hospitals Subject to Outpatient PPS; hospitals must use 13X for ASC claims submitted for OPSS payment -- eff. 7/00)
85x	Special facility or ASC surgery-rural primary care hospital (eff 10/94)

### Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

0636	Drugs requiring specific identification-detailed coding (eff 3/92)
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## CPT/HCPCS Codes

Italicized and/or quoted material is excerpted from the American Medical Association, *Current Procedural Terminology (CPT)* codes.

**See revision history for code updates effective retroactive to 01/01/2010.**

36593	Declot vascular device
96360	Hydration iv infusion, init
96361	Hydrate iv infusion, add-on
<a href="#">96365 - 96379</a>	Ther/proph/diag iv inf, init - Ther/prop/diag inj/inf proc
<a href="#">96401 - 96549</a>	Chemo, anti-neopl, sq/im - Chemotherapy, unspecified
<a href="#">J0120 - J9999</a>	Tetracyclin injection - Chemotherapy drug

## ICD-9 Codes that Support Medical Necessity

Not Applicable

## ICD-9 Codes that DO NOT Support Medical Necessity

Not Applicable

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## Other Information

### Other Comments

Refer to LCD L27473 for general information on drugs and biologicals.

Refer to LCD L27477 for information on Cancer Chemotherapeutic Agents.

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## Revision History

### Revision History Explanation

Date	Article #	Description
01/13/2010	A47797	Article effective 01/14/2010. The following CPT/HCPCS code changes are effective retroactive to 01/01/2010. Code deletions: J0460, J0530, J0540, J0550, J0835, J1565, J7312, and J9170. Code description changes: 96376, J0585, J0587, and J7192. New codes: J0461, J0559, J0586, J0598, J0718, J0833, J0834, J2562, J2793, J2796, J7185, J7325, J9155, J9171 and J9328. Article text updated to reflect the new HCPCS narrative associated with J0585.
10/27/2009	A47797	Article revised effective 10/28/2009. Article revised to clarify that it also addresses Cancer Chemotherapeutic Agents; to clarify guidance regarding infusion time, hydration, and drug wastage; Bill Type Codes 18x, 21X, 22X and 23X added; and CPT/HCPCS codes expanded to include J0120-J9999.
12/12/2008	A47797	Article effective 12/12/2008 for Pennsylvania Part B. Article is now effective for DC Part A and DCMA Part B; Delaware Part A and Part B; Maryland Part A and Part B; New Jersey Part A and Part B; Pennsylvania Part A and Part B. The following CPT/HCPCS code changes will be effective 01/01/2009: Deleted codes 90760, 90761, 90765-90779. Added codes 36593, 96360, 96361, 96365-96379.
11/19/2008	A47797	Article revision effective 11/20/2008. Compendia and related instructions updated in the Article text section, per CR 6191 (non-discretionary update). Please see that section for effective dates for each compendium.
11/14/2008	A47797	Article effective 11/14/2008 for New Jersey Part B and Delaware Part A. Article is now effective for DC Part A and DCMA Part B; Delaware Part A and Delaware Part B; Maryland Part A and Maryland Part B; New Jersey Part A and New Jersey Part B; Pennsylvania Part A.

09/24/2008	A47797	Article revision release date. Typographical errors corrected. Revision effective 09/25/2008.
08/29/2008	A47797	Article effective 09/01/2008 for New Jersey Part A. Effective 09/01/2008, New Jersey Part A will be added to the other jurisdictions already effective: DC Part A and DCMA Part B; Maryland Part A and Maryland Part B; Pennsylvania Part A; and Delaware Part B.
08/01/2008	A47797	Article effective 08/01/2008 for DC Part A, Maryland Part A, and Pennsylvania Part A. Article is now effective for DC Part A and DCMA Part B; Maryland Part A and Maryland Part B; Pennsylvania Part A; and Delaware Part B.
07/11/2008	A47797	Article release date.

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